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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/517,981	03/03/2000	Julie A. Bearcroft	P01952US0	5566

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/517,981	BEARCROFT ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 20-25 and 27-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5, 6</u> . | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-60, 64, drawn to a shaped particle and method of use, classified in class 623, subclass 23.56.
- II. Claims 61-63, drawn to a method of making calcium sulphate dihydrate, classified in class 106, subclass 611.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process that is not made of calcium sulphate dihydrate.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: Fig. 1.

Species IV: Figs. 5A-5D.

Species II: Figs. 3A-3D.

Species V: Figs. 6A-6D.

Species III: Figs. 4A-4D.

Species VI: Figs. 7A-7D.

Species VII: Figs. 8A-8D.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and *a listing of all claims readable thereon*, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Melissa Sistrunk on 1/30/02 a provisional election was made without traverse to prosecute the invention of Group I and Species I,

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claims 1-26, 64. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27-63 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim 9 is objected to because of the following informalities: it appears the claim should depend from claim 4, not 6. Appropriate correction is required.

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Claim R jections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 10, 14, 17, 20, 21, 23, 26, 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Ersek et al. (5258028). Ersek et al. disclose (Fig. 5) a shaped particle with a center portion and at least four tapered extremities projecting from the center portion. Ersek discloses the array of particles have an adequate porosity to allow ingrowth, col. 5, lines 49-56. The particles are used for bone tissue repair, col. 9, lines 54-60. The materials forming the particles can include ceramics and polymers, col. 6, lines 45-57 and the diameter of the particle can be about 3mm, col. 6, lines 31-40.

Claims 1-4, ~~9~~, 10, 17, 20-23, 26, 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Sheppard et al. (WO 94/08912). Sheppard et al. disclose the use of ceramics and polymers for the aggregate or array of particles, page 19, lines 26-28. Figs. 5 and 6 show an array of particles with tapered extremities extending from a center portion. Fig. 2 shows the particle with six extremities. Sheppard also discloses that ceramics can be used in bone replacement and periodontal disease requiring tooth implants, page 32, lines 20, 27. The particles can include ceramics and glasses of which can be interpreted broadly to encompass a substance that enables bone ingrowth, page 19, lines 26-29.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 9, 11-13, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. '028 in view of Chen et al. (6180606). Ersek is explained supra. However, Ersek does not disclose the claimed materials for the particles or composite materials. Chen et al. teach that compositions used in periodontal repair is formed of calcium compounds, col. 2, lines 13-25. Polymers such as polylactic acid can be used for the matrix and composites can also be formed of polymer/ceramic or glass combinations, col. 3, lines 40, 41, 47-50, 60-65. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the suggested materials and combinations as taught by Chen for the particles of Ersek in order to enhance the osteogenic potential of the composition being used.

Claims 15, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. '028 in view of Kondo et al. (JP 171546). Ersek is explained supra. However, Ersek does not disclose the particle diameter in the range of 6mm. Kondo et al. teach forming particles with protruberances or extremities on the surface having a diameter of 8mm, page 3, lines 9, 10. It would have been obvious to one of ordinary

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skill in the art to use the teaching of Kondo to use diameters "about" 6 to 8mm for the particle of Ersek in order to encourage greater tissue ingrowth.

Claims 7, 8, 18, 19, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. '028 in view of Kelly et al. (5676745). Ersek is explained supra. However, Ersek does not disclose the ceramic as gypsum and to use mixtures or to have a porosity between 40-80%. Kelly et al. teach that composites for bone implants or restoration (col. 1, lines 51-59) can be mixed with different materials, col. 2, lines 18-23, 58-62. Kelly also teaches that gypsum can be used for the particles of the composition, col. 4, lines 19-20. The porosity is about 40%, col. 3, lines 3,4. It would have been obvious to one of ordinary skill in the art to use the teachings of Kelly for providing mixtures of materials and having a porosity of about 40% for the particles of Ersek in order to facilitate bone ingrowth within the framework of the implant.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ersek et al. '028. Ersek is explained supra. However, Ersek does not disclose a porosity between 60-80% for the array of particles. It would have been an obvious expedient to have the porosity between 60-80%, since applicant has not disclosed that an array having this specific range of porosity provides an advantage, solves any stated problem or is for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any porosity because bone ingrowth will occur in ^{almost} any pore size.

PP
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 7:30am to 5pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

January 30, 2002

Brian E. Pellegrino

Paul Prebilic

Paul Prebilic

Primary Examiner

TC 3700, AU 3738

**Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01**

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.